

**Notice of Allowability**

Application No.

09/773,866

Examiner

Phillip Gambel

Applicant(s)

THOMAS ET AL

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 7/13/06; 9/15/06.
2. ☒ The allowed claim(s) is/are 21-22, 29-32 renumbered 1-6.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application                                |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                              |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance             |
|  | 9. <input type="checkbox"/> Other _____  |

### **DETAILED ACTION**

1. Applicant's amendment, filed 7/13/06, has been entered.  
Claim 23 has been canceled.  
Claims 1-20 and 25-28 have been canceled previously.

Claims 21, 24, 31, 32 have been amended.

Claims 21- 24 and 29-48 are pending.

Claims 33-48 have been withdrawn previously as being drawn to a non-elected invention(s).

### **EXAMINER'S AMENDMENT**

2. An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.
3. Authorization for this Examiner's Amendment was given in a telephone interview with Andrew Holmes on September 15, 2006.
4. The claims have been amended as attached.

### **REASONS FOR ALLOWANCE**

5. The following is an Examiner's Statement of Reasons for Allowance:

Applicant's amendment, filed 7/13/06, in conjunction with the Examiner's Amendment herein have obviated the previous grounds of rejection. The instant methods of enhancing antigen-presenting cell-mediated cytotoxic T lymphocyte responses with the specific anti-CD40 specific antibodies recited in the instant claims appear to be free of the prior art. Accordingly the instant claims are deemed allowable.

For examination purposes, the claimed "CD40 binding fragments" read on each of "agonist anti-cD40 antibody or a chimeric antibody, humanized antibody or single chain antibody" recited in the instant claims.

Applicant's amendment, filed 7/13/06, has provided for the assurances for the deposit of the claimed biological materials.


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6. Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably accompany the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Phillip Gambel, Ph.D., J.D.  
Primary Examiner  
Technology Center 1600  
September 18, 2006

AMENDMENTS TO THE CLAIMS

1-20. (Canceled)

21. (Currently amended) A method for enhancing a human antigen presenting cell (APC)-mediated human cytotoxic T lymphocyte (CTL) response, comprising stimulating an APC with an agonist anti-CD40 antibody, or a chimeric antibody, humanized antibody, single chain antibody or CD40 binding fragment thereof, or ~~binding fragment thereof, wherein said anti-CD40 antibody or binding fragment~~ which is capable of blocking binding of CD40L on a human T lymphocyte to CD40 on a human APC by 16-88%, ~~and further~~ wherein said anti-CD40 antibody is ~~capable of being~~ produced by a hybridoma with American Type Culture Collection (ATCC) deposit designation PTA-2993, PTA-2994, PTA-2995, PTA-2996, PTA-2997, PTA-2998, or PTA-2999.

22. (Previously presented) The method of claim 31, wherein the antigen presenting cell is a monocyte derived dendritic cell.

23-28. (Canceled)

29. (Previously presented) The method of claim 31, further comprising administering IFN- $\gamma$ .

30. (Currently amended) The method of claim 31, wherein the agonist anti-CD40 antibody, or said chimeric antibody, humanized antibody, single chain antibody or CD40 binding fragment thereof, or ~~CD40 binding fragment thereof~~ is administered by injection.

31. (Currently amended) A method for enhancing an antigen-specific cytotoxic T cell lymphocyte (CTL) response, wherein said CTL is activated with a human antigen presenting cell (APC) and wherein said APC is stimulated via the CD40 receptor with an anti-CD40 antibody, or a chimeric antibody, humanized antibody, single chain antibody or CD40 binding fragment thereof, or binding fragment thereof that which binds to said receptor and blocks binding of CD40L to CD40 by 16-88%, and further wherein said anti-CD40 antibody is ~~capable of being~~ produced by a hybridoma with American Type Culture Collection (ATCC) deposit designation PTA-2993, PTA-2994, PTA-2995, PTA-2996, PTA-2997, PTA-2998, or PTA-2999.

32. (Previously presented) A method for enhancing an antigen specific cytotoxic T lymphocyte (CTL) response according to claim 31, wherein said antibody, or said chimeric antibody, humanized antibody, single chain antibody or CD40 binding fragment thereof, or binding fragment thereof blocks binding of CD40L to CD40 by 16-25%.

33-48. (Cancelled)